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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,016	12/21/2005	Andreas Kubin	SONN:067US/10501772	1126

32425 7590 10/30/2007
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EXAMINER	
MELLER, MICHAEL V	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
10/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,016	KUBIN ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-35* is/are pending in the application.

4a) Of the above claim(s) *21-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-20, 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3-12-07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 12-20, drawn to a composition.

Group II, claim(s) 21-29, drawn to a method of making the composition.

Group III, claim(s) 30-33, drawn to a first method of using the composition.

Group IV, claim(s) 34, drawn to a second method of using the composition.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common element between the groups is known in the art as is evidenced by the cited references herein including but not limited to Cody (see the claims).

During a telephone conversation with Mark Wilson on 2/7/2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 12-20. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 21-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant's election with traverse of Group I, claims 12-20 and now claim 35 in the reply filed on 6/22/2007 is acknowledged. Applicants traverse on the ground(s) that to search the method of using the composition (of Group IV) and the elected Group I (the composition used in that method) would allegedly overlap. This is not found persuasive because there is no special technical feature since the common element between all of the groups is known as is evidenced by the art of record.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 12-14, 19, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cody.

Cody teaches a soft gelatin capsule containing Hypericum performatum (which contains hypericin) and polyvinylpyrrolidone (PVP), see col. 3, lines 20-30, col. 5, lines 50-end, the claims.

Applicant argues that Cody does not teach that the hypericin is isolated but it is noted at col. 4, lines 35-55, that hypericin is "standardized" to comprise 0.3 % by weight hypericin, which implies that the hypericin was clearly isolated from the rest of the plant.

Further, the claims do recite "comprising" language which leaves the claim open to other ingredients being isolated.

Further, applicant argues that the reference does not teach a water soluble complex of hypericin and PVP, but the reference does as applicant has done by combining the PVP and the hypericin which would inherently have the same properties as applicant's invention, namely, be water soluble.

Claims 12-14, 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Bombardelli et al. or Castillo et al.

Bombardelli teaches a tablet containing Hypericum performatum (which contains hypericin) and polyvinylpyrrolidone (PVP), see paragraph 41, and the claims.

Castillo teaches that Hypericum perforatum and PVP are together in a tablet, see paragraphs 112 and 116.

Applicant argues as above that the hypericin was not isolated in the references. Bombardelli teaches on page 3, paragraph 39, that the extracts were filtered and concentrated under vacuum to provide 0.4 % of hypericin, which clearly was isolated from the rest of the plant. Further, the claims do recite "comprising" language which leaves the claim open to other ingredients being isolated.

Similarily, in Castillo, applicant argues that the hypericin was not isolated, but this is not well taken since Castillo clearly teaches that in paragraph 34, that hypericin was standardized to contain 0.05% to 2% hypericin. This clearly was isolated from the rest of

the plant. Further, the claims do recite "comprising" language which leaves the claim open to other ingredients being isolated.

Further, applicant argues that the reference does not teach a water soluble complex of hypericin and PVP, but the reference does as applicant has done by combining the PVP and the hypericin which would inherently have the same properties as applicant's invention, namely, be water soluble.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-20, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cody in view of JP 409262279.

Cody teaches a soft gelatin capsule containing Hypericum performatum (which contains hypericin) and polyvinylpyrrolidone (PVP), see col. 3, lines 20-30, col. 5, lines 50-end, the claims.

Cody does not teach that the PVP is 10,000 to 40,000 g/mol.

JP teaches that PVP is routinely used for material which is suitable for the human body at a molecular weight of 20,000 to 150,000, see abstract.

Thus, it would have been obvious to one of ordinary skill in the art to use such a molecular weight of PVP since such a molecular weight range is well known to be used

when contacting the human body. Further it would have been obvious to use the amounts claimed in the composition since the result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Applicant argues that JP does make up for the deficiencies of Cody as noted above.

As discussed above, Cody does meet the claimed invention.

Claims 12-20, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et.al. or Castillo et al. in view of Cody and JP 409262279.

Bombardelli teaches a tablet containing Hypericum performatum (which contains hypericin) and polyvinylpyrrolidone (PVP), see paragraph 41, and the claims.

Castillo teaches that Hypericum perforatum and PVP are together in a tablet, see paragraphs 112 and 116.

Bombardelli and Castillo do not teach that the PVP has the claimed molecular weight, the other amounts in the claims, or that the composition is in a gel form.

Cody teaches a soft gelatin capsule containing Hypericum performatum (which contains hypericin) and polyvinylpyrrolidone (PVP), see col. 3, lines 20-30, col. 5, lines 50-end, the claims.

JP teaches that PVP is routinely used for material which is suitable for the human body at a molecular weight of 20,000 to 150,000, see abstract.

Thus, it would have been obvious to one of ordinary skill in the art to use such a molecular weight of PVP since such a molecular weight range is well known to be used when contacting the human body as evidenced by JP. To use a gel composition instead of a tablet is also obvious since Cody makes it clear that either can be used, see col. 5, line 50-col. 6, line 60. Further it would have been obvious to use the amounts claimed in the composition since the result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Applicant argues that JP does make up for the deficiencies of Bombardelli or Castillo as noted above.

As discussed above, Bombardelli and Castillo do meet the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller
Primary Examiner
Art Unit 1655